

Human patient simulation education in the nursing management of the mechanically ventilated patient – a randomized controlled trial

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## Summary

**Background:** Knowledge among critical care nurses and their adherence to evidence-based guidelines for preventing ventilator-associated pneumonia have been reported to be low.

**Aim:** To evaluate the effectiveness of human patient simulation (HPS) education in the nursing management of mechanically ventilated patients. The primary outcomes measured between randomly allocated intervention and control groups were participant knowledge of and skill in adhering to ventilator bundle.

**Methods:** A prospective, parallel randomized controlled trial with repeated measurements was conducted in a 22-bed adult mixed medical-surgical intensive care unit in Finland from February to October 2012. Thirty ( $n = 30$ ) critical care nurses were allocated evenly to intervention and control groups ( $n = 15$  each). The effectiveness of HPS education was evaluated through the validated Ventilator Bundle Questionnaire (VBQ) and Observation Schedule (VBOS) at the baseline and repeated twice respectively after the clinical and simulation settings.

**Findings:** After HPS education, the average skill scores (VBOS) in the intervention group increased significantly from 46.8 to 60.0% of the total score in the final post-intervention observation. In the average skill scores, a linear mixed model identified significant time ( $p_t < 0.001$ ) and group differences ( $p_g = 0.03$ ) and time–group interactions ( $p_{t*g} = 0.02$ ) between the study groups after the HPS education. In contrast, the model did not identify any significant change over time ( $p_t = 0.29$ ) or time–group interactions ( $p_t = 0.69$ ) between groups in average knowledge scores (VBQ).

**Conclusion:** The study identified significant transfer of learned skills to clinical practice following HPS education but no impact on the level of participants' factual knowledge.

**Keywords:** Critical Care, Human patient simulation, Ventilator bundle, Knowledge, Skills

## Introduction

Ventilator-associated pneumonia (VAP) is the most frequently encountered device-associated nosocomial infection in critical care settings <sup>1-2</sup>, causing substantial morbidity, a two-fold increase in mortality rate <sup>3</sup>, excess costs <sup>4</sup>, and prolonged lengths of ventilator days <sup>3</sup> and intensive care unit (ICU) and hospital stays <sup>3,5</sup>.

Knowledge among critical care nurses <sup>6-9</sup> and their adherence to <sup>10</sup> evidence-based guidelines for preventing VAP have been reported to be low, which may jeopardize patient safety and thus quality of care <sup>11</sup>. Previous educational interventions have been linked to significant improvements in the level of knowledge and skill in adhering to guidelines and a significant decrease in adverse clinical outcomes <sup>12-13</sup>.

Simulation is an exciting application of advanced technology in healthcare staff education <sup>14</sup> that offers a unique mode for experimental learning <sup>15</sup> and evaluation <sup>14-16</sup>, yet the effectiveness of human patient stimulation (HPS) education in critical care settings is poorly documented <sup>17</sup>. Previous prospective, experimental <sup>18</sup> and quasi-experimental <sup>19-21</sup> studies have demonstrated statistically significant improvements in participant knowledge, teamwork, leadership <sup>21</sup>, and clinical skills <sup>18-21</sup> immediately after HPS education. However, longitudinal randomized controlled studies are lacking that evaluate the effectiveness on nursing continuing education of HPS in infection control or that identify the transfer of learned skills to clinical practice.

The aim of this study was to evaluate how knowledge about and skills for managing the mechanically ventilated patient differ between randomly allocated intervention and control groups before and after HPS education in both the simulation environment and clinical setting. The hypothesis was that in the intervention group, knowledge and skill in adhering to ventilator bundle (VB; a package of evidence-based interventions to prevent VAP) <sup>22-24</sup> might increase compared to control group after the HPS education.

## Methods

### Study design

A single-center, prospective, parallel randomized controlled trial (RCT) with repeated measurements was conducted to evaluate the effectiveness of HPS education in the nursing management of mechanically ventilated patients. The primary outcomes measured were how participant knowledge and skills in adhering to the VB compared between randomly allocated intervention and control groups before and after educational intervention. The reporting of this study complies with the CONSORT (Consolidated Standards of Reporting Trials) statement <sup>25</sup>.

### Sample and setting

The study was conducted in a single academic center in a 22-bed adult mixed medical-surgical ICU in Finland from February to October 2012. According to the Medical Research Act (488/1999 and amendments 295/2004), approval of the local ethics committee is not required for studies focusing on healthcare staff. However, the study protocol was approved by the relevant academic center in the fall of 2011.

Randomly selected critical care nurses were invited to participate via letter and electronic mail. In addition, nurse managers informed critical care nurses at staff meetings of study availability and encouraged completion. Inclusion criteria were: holding a degree qualification as a registered nurse and being a direct care provider (bedside). Written informed consent from participants was obtained prior to inclusion in the study (Declaration of Helsinki 2008).

A sample size of  $n = 40$  was calculated to detect a 20% [2.74, standard deviation (SD) 2.66 points] difference between the study groups in the average skill score [26] [with significance level ( $\alpha$ ) = 0.05, power ( $1-\beta$ ) = 90%, and dropout level = 20%]. Participants were allocated to intervention ( $n = 20$ ) and control ( $n = 20$ ) groups according to a computer-generated randomization list separately in two age-based strata ( $\leq 35$  and  $> 35$  years) according to the median age of the study population.

## Intervention and study protocol

HPS education began with a brief bedside introduction (20 minutes) from the simulation educators, giving a hands-on explanation of the simulation process (i.e., briefing, simulated scenario, and debriefing) and use of the HPS mannequin (HAL®, Gaumard). During the 10-minute scenario, participants were asked to engage in all of the essential nursing interventions to prevent VAP for an enterally fed, mechanically ventilated patient with an artificial airway, starting from respiratory management. During the simulations, the software of the HPS mannequin was programmed to cough and change vital signs (e.g., heart and respiratory rates, blood and airway pressures, and peripheral oxygen saturation).

Participants had access to all necessary equipment used in the ICU environment (e.g., patient monitors, respirator, oxygen, endotracheal suctioning device, and oral care equipment) and could ask the facilitator questions. Only the intervention group received verbal feedback and participated in a 60-minute structured debriefing based on the effectiveness of the VB. During the debriefing, participants could ask questions and engage in discussion with the simulation educators.

The measurements were completed three times for both groups. After the baseline measurement, the intervention group underwent HPS education. Then the measurements were performed similarly for the intervention and control groups. The initial post-intervention measurements (3 months after the intervention) were conducted in the simulation environment (follow-up I), and the final post-intervention measurements (6 months after the intervention) were made during the morning shift (07:00–15:00) in clinical practice (follow-up II). Participants were evaluated while managing adult, mechanically ventilated patients using a direct, structured, non-participatory method of observation, which is a purposeful data collection method, particularly for recording participant behavior.<sup>27</sup>

Participant skills were measured by an 86-item, highly structured Ventilator Bundle Observation Schedule (VBOS), designed to evaluate the ability of critical care nurses to adhere to the VB in clinical practice. In addition, a 49-item multiple-choice Ventilator Bundle Questionnaire (VBQ) was given to both groups at the end of the observational sessions to evaluate factual knowledge of the critical care nurses about the VB, which was defined as the basic knowledge required to treat mechanically ventilated patients. The content of the VBQ and VBOS was used to define two nursing measures for the management of adults with VAP: 1) intubation and mechanical ventilation (i.e., daily sedation “vacations” and assessment of readiness to extubate and facilitate accelerated weaning); and 2)

prevention of airway colonization (i.e., body positioning, adequate enteral feeding and cuff pressure, daily oral care with chlorhexidine, appropriate hand hygiene, and updated endotracheal suctioning practices) [Jansson M, Ala-Kokko T, Syrjälä H, Kyngäs H. The development and psychometric testing of ventilator bundle questionnaire and observation schedule. Manuscript]. The inter-rater procedure was used to collect prospective, observational data in clinical nursing practice. Moreover, the prospectively collected data were reviewed retrospectively from video and clinical records.

#### Statistical analysis

SPSS 18.0 for Windows (SPSS Inc., Chicago, IL, USA) and SAS for Windows (version 9.2, SAS Institute Inc., Cary, NC, USA) were used for data analyses. Analyses were conducted by a biostatistician who was unaware of group identity. All participants were included in the analysis in the groups to which they were originally assigned (intention-to-treat analysis).<sup>25</sup>

The repeatedly measured data were analyzed using a linear mixed model with a covariance pattern model. *P* values reported for repeatedly measured data are as follows: p-time ( $p_t$ ), the overall change over time; p-group ( $p_g$ ), the average between-group difference; and p-time\*group ( $p_{t*g}$ ), the interaction between time and group. Independent-sample t-tests and Fisher's exact tests were used to determine whether characteristics or baseline test scores of participants who withdrew differed from those of participants who completed all of the study procedures. Moreover, Spearman correlation coefficients were used to determine whether mean age correlated with test scores. A two-tailed *P* value less than 0.05 was considered statistically significant.

## Results

Thirty ( $n = 30$ ) out of forty ( $n = 40$ ) initially randomized critical care nurses participated in the baseline measurements (Table I), of whom twenty-three ( $n = 23$ ) completed all the study procedures (Figure 1). The main reasons for withdrawal were declining to participate and illness.

According to the linear mixed model, average knowledge scores (VBQ) within either groups did not change statistically (Table II). However, the intervention group had higher scores ( $p_g = 0.05$ ) over the whole study period. In the intervention group, the average skill scores (VBOS) increased significantly after HPS education from 46.8 to 60.0% of the total score in the final post-intervention observation (Table III). The significant changes over time were related to intubation and mechanical ventilation ( $p_t < 0.001$ ) and the prevention of airway colonization ( $p_t = 0.02$ ). The significant time group interactions were related to the prevention of airway colonization ( $p_{t*g} = 0.02$ ). In the control group, the average skill scores did not increase during the study period. Both groups had repeatedly low scores for appropriate hand hygiene as related to the knowledge and skill scores.

## Discussion

This study is the first longitudinal randomized controlled trial to evaluate the effectiveness of HPS education in infection control on nursing continuing education and identified significant transfer of learned skills to clinical nursing practice in the ICU. On the other hand, HPS education did not affect the level of factual knowledge among participants.

Despite the lack of clinical outcome endpoints <sup>20</sup>, our longitudinal study demonstrated significant advantages of short-term HPS education for critical care nursing skills in managing mechanically ventilated patients. Contrary to previous studies <sup>18, 21</sup>, the primary outcomes were assessed both in a simulation environment and in a real-life clinical situation, and the effects persisted over 6 months of follow-up. These results suggest a real-world impact on clinical outcomes by reducing preventable errors (i.e., airway colonization) that could potentially result in harm (e.g., incidence of VAP, prolonged length of mechanical ventilation and stays).

The average skill score (VBOS) in the baseline measurement was 47.8% of the total score. The majority of participants had no previous experience with simulation education, which may explain these low baseline values <sup>28</sup>. The significant time group interactions in the skill scores were related to infection control practices aimed preventing the airway colonization (i.e., elevation of the head of the bed by 30° to 45°, adequate enteral feeding, maintenance of optimal cuff pressure, adequate hand hygiene), whereas the significant changes over time associated with intubation and mechanical ventilation (e.g., sedation assessment, daily sedation vacation) might be attributable to well-implemented guidelines in clinical nursing practice.

In contrast to the results of a previous quasi-experimental intervention study <sup>29</sup>, the lack of significant findings related to endotracheal suctioning practices was a surprising result. Generally in the previous studies, the significant advantages of HPS education were seen in measurements performed immediately post-intervention with a methodology combining real-time audiovisual, individualized, and tailored performance feedback <sup>18, 21, 29</sup> after standardized lecture and practical demonstration <sup>19, 29</sup> or repeated scenarios <sup>21</sup>.

The average knowledge score (VBQ) was 54.4% of the total score whereas previous international surveys reported average knowledge scores ranging from 41.2% <sup>6</sup> to 78.1% <sup>8</sup>. The variability of results among the published studies might be attributable to differences between the specific healthcare delivery models <sup>8</sup>, routine critical care



nursing duties <sup>7, 30</sup>, and local and international guidelines as well as views on good practice and/or a lack of consistent policy <sup>7</sup>.

Our study also diverged from previous findings in not identifying significant advantages of HPS education in terms of the level of factual knowledge among participants. However, we did not measure the immediate effects of HPS education; our first measurements were at 3 months after intervention. The variability of findings among the published studies <sup>18, 20-21, 29</sup> might result from the lack of a universal method for outcome measurements (i.e., standardized scenarios and instruments, variations in the dosing of simulation-based education, and standardized measurement and follow-up times); however, the level of knowledge was evaluated in the current work through a multiple-choice questionnaire, which is assumed to be an appropriate method of objectively measuring factual knowledge <sup>27, 31-32</sup>. Nevertheless, HPS education has not proved to be a clearly superior method compared to conventional approaches, such as traditional didactic lecture <sup>20</sup> or audiovisual feedback <sup>18</sup>.

The basis for the statistically significant difference in the average knowledge scores within the groups over the whole study period remains unclear. However, there was no significant correlation between the mean age and test scores, which is known to influence the level of knowledge <sup>6-7, 30</sup> and attitudes toward clinical practice guidelines <sup>33-34</sup>.

The major study limitations and the potential source for bias are related to the generalizability and relatively small sample size. This study focused on registered nurses, and the results may not be applicable to physicians or nursing students. The lack of significant enhancement of participant knowledge might have been attributable to the limited sample sizes and late measurements. However, the study population was statistically sufficiently powered for skill scores. The withdrawal rate between the groups varied from 13.3% (intervention group) to 33.3% (control group). However, average knowledge scores relative to total score or demographic details at the baseline did not differ significantly between those who withdrew and those who completed all aspects of the study.

In earlier studies, intervention and control groups have typically worked in different units. Of interest here is that the differences in skills observed in our study population were from intervention and control participants who were working in the same ICU. Further research is necessary to determine optimal preparation, execution, and dosing of simulation education. In addition, the relationship between HPS education and clinical outcomes should be taken into account. This study also has direct implications for everyday practice in our ICU. Despite continuing emphasis on the importance of hand hygiene in infection prevention, the knowledge and skill scores in this area clearly demonstrated

that our results agree with those in the hand hygiene literature, and we once again have to implement a new hand hygiene campaign in our ICU.

### **Conclusions**

HPS education significantly improved skills among critical care nurses in managing the mechanically ventilated patient, an improvement that persisted at 6 months of follow-up.

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### **Conflict of interest**

No conflict of interest has been declared by the authors.

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### **Author contributions**

MJ, TAK, PO, MM, HS, and HK contributed to the study design. MJ contributed to data collection. MJ and PO performed the data analysis. MJ, TAK, PO, MM, HS, and HK contributed to data interpretation and manuscript preparation.

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**Table I** Characteristics of participants (*n* = 30) at baseline

Characteristics	Intervention group ( <i>n</i> = 15)	Control group ( <i>n</i> = 15)
Age: mean y (SD)	37.07 (11.49)	33.80 (9.34)
Sex		
Female: <i>n</i> (%)	11 (73.3)	10 (66.7)
Education		
Bachelor's degree: <i>n</i> (%)	14 (93.3)	15 (100.0)
Master's degree: <i>n</i> (%)	1 (6.7)	0 (0.0)
Experience in the current ICU: mean y (SD)	9.27 (9.79)	7.85 (8.53)

**Table II** Summary of the knowledge scores (VBQ<sup>1</sup>) before and after human patient simulation education

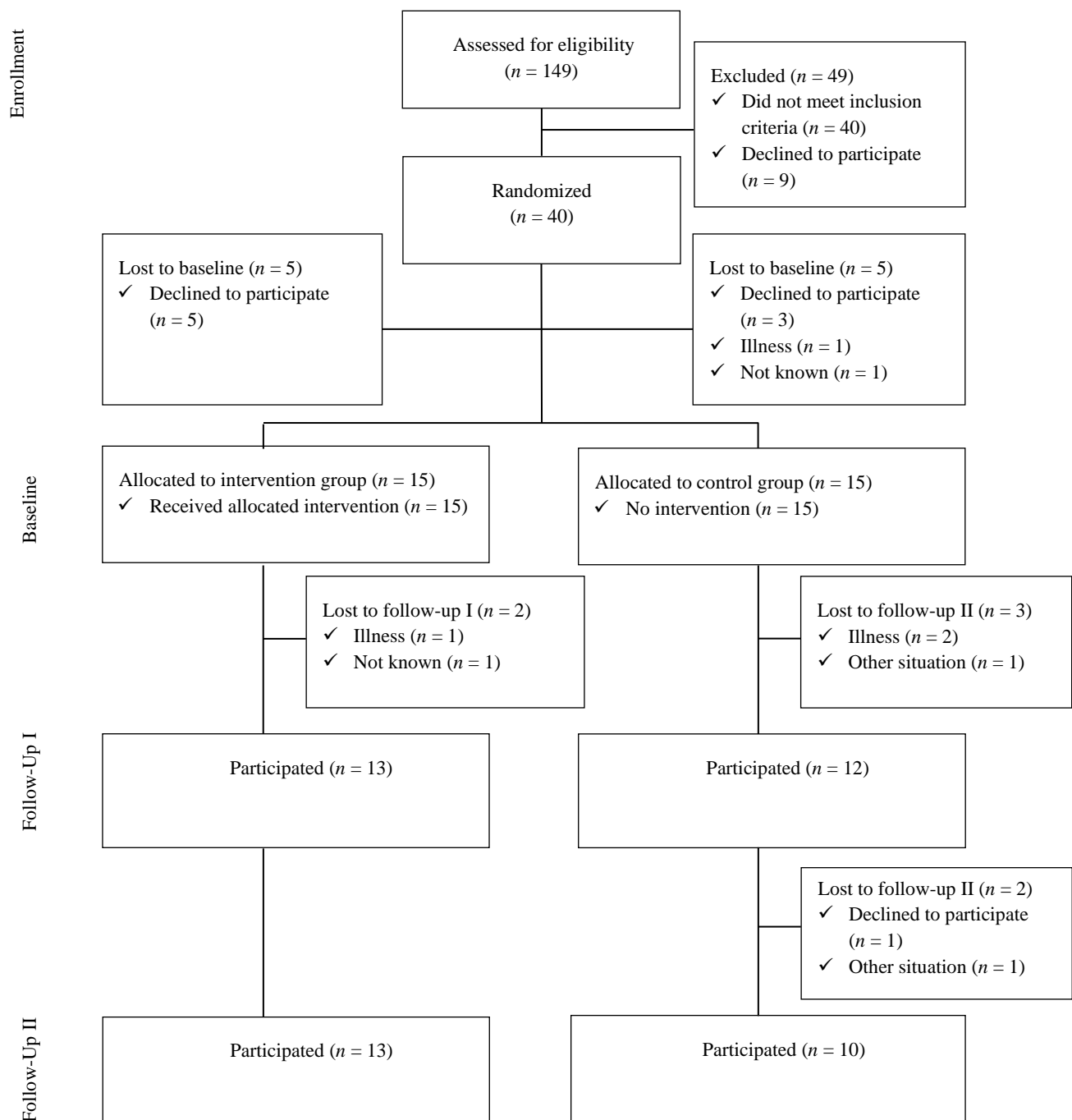
Outcome	Baseline score mean (SD) <sup>2</sup>		Follow-up I score mean (SD) <sup>2</sup>		Follow-up II score mean (SD) <sup>2</sup>		$p_t^3$	$p_g^4$	$p_{t*g}^5$
	Intervention group ( <i>n</i> = 15)	Control group ( <i>n</i> = 15)	Intervention group ( <i>n</i> = 13)	Control group ( <i>n</i> = 12)	Intervention group ( <i>n</i> = 13)	Control group ( <i>n</i> = 10)			
Total score (range 0–37)	21.67 (2.38)	18.60 (3.25)	23.08 (3.50)	19.00 (2.99)	22.38 (4.72)	19.10 (2.23)	0.29	0.005	0.69
Intubation and mechanical ventilation							0.19	0.01	0.22
Daily “sedation vacations” and assessment of readiness to extubate (range 0–5)	3.00 (1.41)	2.20 (1.42)	3.08 (1.17)	2.58 (0.99)	3.15 ( 1.14)	2.40 (0.84)			
Facilitate accelerated weaning (range 0–7)	5.07 (0.59)	4.67 (0.90)	5.75 (0.97)	4.33 (1.30)	5.15 (1.14)	4.90 (0.57)			
Prevention of airway colonization							0.64	0.02	> 0.9
Aspiration, body position, and enteral feeding (range 0–4)	3.60 (0.51)	3.47 (0.64)	3.33 (0.65)	3.25 (0.62)	3.46 (0.66)	3.00 (0.47)			
Daily oral care with chlorhexidine (range 0–5)	2.20 (0.56)	2.20 (0.56)	3.15 (1.07)	1.92 (0.79)	3.00 (1.23)	1.80 (0.79)			
Endotracheal suctioning practices (range 0–14)	6.60 (1.50)	5.53 (2.20)	6.92 (SD 1.66)	6.08 (1.24)	6.85 (2.30)	6.20 (1.14)			
Appropriate hand hygiene (range 0–2)	1.20 (SD 0.78)	0.53 (SD 0.83)	1.08 (0.86)	0.83 (0.72)	0.77 (0.83)	0.80 (0.92)			

<sup>1</sup> VBQ = ventilator bundle questionnaire. <sup>2</sup> Values are given as mean with standard deviation (SD). *P* values reported for repeatedly measured data are as follows: <sup>3</sup> the overall change over time ( $p_t$ ), <sup>4</sup> the average group difference ( $p_g$ ), and <sup>5</sup> the interaction between time and group ( $p_{t*g}$ ). A  $P < 0.05$  is considered significant.

**Table III** Summary of the skill scores (VBOS<sup>1</sup>) related to intubation and mechanical ventilation before and after human patient simulation education

Outcome	Baseline score mean (SD) <sup>2</sup>		Follow-up I score mean (SD) <sup>2</sup>		Follow-up II score mean (SD) <sup>2</sup>		$p_t^3$	$p_g^4$	$p_{t*g}^5$
	Intervention group ( <i>n</i> = 15)	Control group ( <i>n</i> = 15)	Intervention group ( <i>n</i> = 13)	Control group ( <i>n</i> = 12)	Intervention group ( <i>n</i> = 13)	Control group ( <i>n</i> = 10)			
Total score (range 0–60)	28.07 (3.85)	29.33 (3.92)	31.85 (3.31)	29.50 (2.84)	36.00 (4.04)	31.50 (4.33)	< 0.0001	0.03	0.02
Intubation and mechanical ventilation							< 0.0001	0.08	> 0.9
Daily “sedation vacations” and assessment of readiness to extubate (range 0–3)	0.60 (0.63)	0.13 (0.35)	0.77 (0.93)	0.25 (0.45)	1.62 (0.96)	1.20 (0.63)			
Facilitate accelerated weaning (range 0–3)	0.87 (0.52)	0.93 (0.59)	0.85 (0.56)	0.92 (0.29)	2.08 (0.86)	2.10 (0.74)			
Prevention of airway colonization							0.02	0.09	0.02
Aspiration, body position, and enteral feeding (range 0–3)	1.47 (0.74)	1.53 (0.52)	2.08 (0.64)	1.83 (0.39)	2.54 (0.52)	2.70 (0.48)			
Daily oral care with chlorhexidine (range 0–13)	5.43 (1.51)	5.50 (1.56)	5.92 (1.12)	5.33 (0.78)	6.69 (1.25)	4.78 (1.39)			
Endotracheal suctioning practices (range 0–26)	15.20 (2.21)	16.40 (2.10)	17.62 (3.23)	16.50 (2.07)	16.00 (2.45)	15.70 (1.64)			
Appropriate hand hygiene (range 0–12)	4.87 (1.51)	5.20 (2.24)	4.62 (1.19)	4.67 (1.07)	7.08 (1.94)	5.50 (1.90)			

<sup>1</sup> VBQ = ventilator bundle questionnaire. <sup>2</sup> Values are given as mean with standard deviation (SD). *P* values reported for repeatedly measured data are as follows: <sup>3</sup> the overall change over time ( $p_t$ ), <sup>4</sup> the average group difference ( $p_g$ ), and <sup>5</sup> the interaction between time and group ( $p_{t*g}$ ). A *P* < 0.05 is considered significant.



**Figure 1.** Flow chart of the progress through the phases of a parallel randomized trial of two groups.